REMARKS

The Office Action mailed November 22, 2006, has been received and reviewed. Claims 51 through 75 are currently pending in the application. Claims 51 through 75 stand rejected. Applicants have amended claims 65 and 71, and respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 4,623,330 to Laby et al.

Claims 51 and 52 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laby et al. (U.S. Patent No. 4,623,330). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 4,623,330 to Laby et al. in view of U.S. Patent No. 4,360,019 to Portner et al., U.S. Patent No. 5,238,687 to Magruder et al. and further in view of U.S. Patent No. 5,519,002 to Mia

Claims 51 through 75 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Laby et al. (U.S. Patent No. 4,623,330) in view of Portner et al. (U.S. Patent No. 4,360,019), Magruder et al. (U.S. Patent No. 5,238,687) and further in view of Mia (U.S. Patent No. 5,519,002). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must

> be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Independent claims 51 and 52 are drawn to implantable devices for delivering an active agent to a fluid environment of use, the devices comprising a reservoir and a back diffusion regulating outlet for delivering fluid from the reservoir to the fluid environment, wherein the back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back-diffusion of external fluid through the flow path, and wherein the helical flow path has a length of about 2 to about 7 cm (claim 51) and has a diameter of about 0.003 to about 0.020 inches (claim 52). Independent claim 55 is drawn to a fluid-imbibing device that includes a water-swellable semipermeable material that is received in sealing relationship with an interior surface of an open end of an implantable reservoir, wherein the semipermeable material includes circumferential ridges. Independent claim 61 is drawn to a fluid-imbibing device that includes a water-swellable, semipermeable, substantially cylindrical plug received in sealing relationship with an interior surface of an open end of an implantable reservoir at the open end, wherein the plug has a plurality of circumferential ridges. Independent claim 65, as amended, is drawn to an implantable LHRH agonist delivery system including a water-swellable agent formulation within a reservoir and a back diffusion regulating outlet having a helical flow path arranged to allow the LHRH agonist to be delivered from the reservoir at a desired flow rate. Independent claim 71 is drawn to a fluid-imbibing device that includes a water-swellable semipermeable material that is received in sealing relationship with an interior surface of an open end of an implantable reservoir, a back diffusion regulating outlet having a helical flow path, wherein the semipermeable material is a substantially cylindrical plug which expands radially upon hydration to provide a friction fit and expands longitudinally to displace the active agent.

Laby et al. discloses a syringe device that is modified to use a spring (instead of a shaft attached to a plunger) to move a plunger. The syringe device includes a hollow body portion

comprising a cylindrical tube open at one end, the other end having a base supporting a helical spring to which a plunger is attached, which plunger is capable of being urged by the spring toward the opening. However, Laby et al. does not disclose a back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back-diffusion of external fluid through the flow path, and wherein the helical flow path has a length of about 2 to about 7 cm or a diameter of about 0.003 to about 0.020 inches, as required in claims 51 and 52, respectively. Laby et al. is limited to describing a helical spring that is attached to a plunger in order to urge the plunger toward the opening. The spring is not a back diffusion regulating outlet having a helical flow path. Additionally, as expressly described in Laby et al., the device comprises a "hypodermic syringe barrel 41 which has the usual flange 42 at its open end 43 and a nozzle portion 44 at the other end which normally receives the hypodermic needle." (See Laby et al., Col. 5, lines 16-20 and Fig. 1D). As clearly described and illustrated, the device of Laby et al. has an outlet that is not back-diffusion regulating and does not have a helical flow path.

Portner is relied upon as teaching an implantable infusion system for delivering drugs that includes "a valve which is spring-loaded in the normally closed position" and is relied upon as teaching use of membranes for allowing injection of a drug supply into a reservoir means.

Magruder is relied upon as disclosing a delivery implantable device that includes a sleeve to protect the delivery device from transient mechanical forces. The composition of the sleeve is said to be a semipermeable material.

Mia is relied upon as disclosing use of LHRH agonists and administration of LHRH agonists through implants to prevent conception in mammals.

As acknowledged by the Examiner, Laby et al. does not disclose a back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back-diffusion of external fluid through the flow path, and wherein the helical flow path has a length of about 2 to about 7 cm or a diameter of about 0.003 to about 0.020 inches, as required in claims 51 and 52, respectively. Laby et al. is limited to describing a helical spring that is attached to a plunger in order to urge the plunger toward the opening. The spring is not a back diffusion regulating outlet having a helical flow path. Additionally, as

expressly described in Laby et al., the device comprises a "hypodermic syringe barrel 41 which has the usual flange 42 at its open end 43 and a nozzle portion 44 at the other end which normally receives the hypodermic needle." (See Laby et al., Col. 5, lines 16-20 and Fig. 1D). As clearly described and illustrated, the device of Laby et al. has an outlet that is not back-diffusion regulating and does not have a helical flow path. Thus, Laby et al. actually teaches away from the present invention, as it relies on use of a plunger attached to a spring to urge the plunger toward an opening that has no back diffusing mechanism. In contrast, the rate of delivery is controlled by the tension on the spring and movement of the plunger relative to the force applied by the spring, and not a back diffusion regulating outlet with helical flow paths.

The relied-upon sections of Magruder, disclosing a semipermeable membrane, do not overcome the deficiencies of Laby et al., as Magruder does not disclose a back diffusion regulating outlet has a helical flow path selected so that a length of the helical flow path is sufficient to prevent back diffusion of external fluid through the flow path. Additionally, because Magruder relates to a device that includes a sleeve to protect the delivery device from transient mechanical forces created by an expandable driving member, there is no motivation to combine Magruder with Laby et al., as the latter is drawn to a spring-activated syringe device that does not require an expandable driving member for activation in place of the spring activated mechanism. This lack of motivation to combine references is likewise applicable to the obviousness rejections for all of the pending claims in the present application, as discussed below. Likewise, Mia does not assist in overcoming the recitations of claims 51-54, as it is simply relied upon as teaching use of LHRH as conception preventatives. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection to claims 51-54. Finally, Portner does not assist in overcoming the recitations of claims 51-54, as it does not teach or suggest a back diffusion regulating outlet that has a helical flow path that is designed to prevent back diffusion. Instead, Portner teaches a spring-loaded valve 41 that prevent back flow. Because Portner relies on a spring-loaded valve to prevent back diffusion, it actually teaches away from the concept of using a helical flow path regulating outlet, as required in claims 51-54.

As with claims 51-54, independent claims 65 and 71, as amended, require a water-

swellable agent formulation within a reservoir and a back diffusion regulating outlet having a helical flow path and arranged to allow an active agent (LHRH agonist in claim 65) to be delivered from the reservoir at a desired flow rate. For the same reasons presented with regard to claims 51-54, claim 65 (and claims 66-70 depending therefrom), and claim 71 (and claims 72-75 depending therefrom) are not obvious in view of Laby et al., Magruder, Portner, and Mia.

As previously discussed, claim 61 (and claims 62-64 depending therefrom), requires a water-swellable, semipermeable, substantially cylindrical plug received in sealing relationship with an interior surface of an open end of an implantable reservoir at the open end, wherein the plug has a plurality of circumferential ridges. None of Laby et al., Magruder, Portner, and Mia, either alone or in combination, teach or suggest a water-swellable, semipermeable, substantially cylindrical plug within an implantable reservoir that has a plurality of circumferential ridges. Instead, Laby et al. relies on a diaphragm 46 and a pair of clamping rings 47, 48 to provide a seal in the open end of the syringe, Portner relies on an exterior housing 22 to provide containment for the contents of the implantable infusion devise, and Magruder relies on enclosed rear end to provide containment for the contents of the delivery device. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection to claims 61-64.

As previously discussed, claim 71 (and claims 72-75 depending therefrom), requires a water-swellable semipermeable material is a substantially cylindrical plug which expands radially upon hydration to provide a friction fit and expands longitudinally to displace the active agent, and a back diffusion regulating outlet having a helical flow path. None of Laby et al., Magruder, Portner, and Mia, either alone or in combination, teach or suggest a substantially cylindrical plug which expands radially upon hydration to provide a friction fit and expands longitudinally to displace the active agent, or a back diffusion regulating outlet having a helical flow path. Instead, Laby et al. relies on a diaphragm 46 and a pair of clamping rings 47, 48 to provide a seal in the open end of the syringe, and on a spring to urge the plunger or piston 5 toward an opening in order to provide delivery of an active agent. Portner relies on an exterior housing 22 to provide containment for the contents of the implantable infusion devise. Magruder relies on enclosed rear end to provide containment for the contents of the delivery device. Notably, none of the references teaches or suggests a back diffusion regulating outlet having a

helical flow path. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection to claims 71-75.

ENTRY OF AMENDMENTS

The amendments to claims 65 and 71 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments do not raise new issues or require a further search.

CONCLUSION

Claims 51-75 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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Date: February 22, 2007
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